International Organization for Standardization   International Accreditation Forum

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ISO 9001 Auditing Practices Group
Guidance on:

Evidence collection

The following information is intended to provide guidance to certification body auditors on how to collect evidence and how to evaluate the collected audit evidence against audit criteria.

Introduction

According to the definition, an audit is a "process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled".

That means that the competent auditor will prepare for the audit in order to know what kind of evidence he or she needs to look for, and will be able to seek out that evidence rather than requiring the auditee to "serve up the evidence on a plate".

Guidance

The competent auditor will take care of the following aspects during the audit planning:

   a) Comprehend the auditee's structure, business and management practices.
   b) Understand the auditee's processes
   c) Risk based thinking relevant to the industry sector or specific to the organization
   d) Pre-evaluation of statutory and regulatory requirements
   e) Consider the effect of the audit activities on the auditee's processes
   f) Identify possible audit evidence to look for in the audit work documents
   g) Adequate time allocation

During the audit realization, it is the auditor who has to evaluate compliance or non-compliance based on the audit evidence collected. That means that if the auditor is not capable of finding evidence of conformity it should not necessarily be taken to infer that the auditee does not comply with the audit criteria.

During the audit, the auditor should always keep in mind the definition of "audit evidence" and the principle of an "evidence-based approach":

Objective evidence, as defined in ISO 9000, is "data supporting the existence or verity of something. Objective evidence can be obtained through observation, *measurement, test,* or

by other means. Objective evidence for the purpose of *audit* generally consists of *records*, statements of fact or other information which are relevant to the *audit criteria* and verifiable."

Evidence-based approach: the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process.

Audit evidence should be verifiable. It will in general be based on samples of the information available since an audit is conducted during a finite period of time and with finite resources. An appropriate use of sampling should be applied, since this is closely related to the confidence that can be placed in the audit conclusions.

Auditors should be aware that objective evidence does not necessarily depend on the existence of documented information, except where specifically mentioned in ISO 9001. In other cases is up to the organization to determine what documented information is necessary in order to provide this objective evidence.

It is the organization's responsibility to provide objective evidence of conformity. Organizations may be able to demonstrate conformity without the need for extensive documented information.

To claim conformity with ISO 9001:2015, the organization has to be able to provide objective evidence of the *effectiveness* of its processes and its quality management system.

The competent auditor will collect audit evidence in the places where the activities are taking place, and preferably in real time, including samples of all shifts and representative sites and processes.

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For further information on the ISO 9001 Auditing Practices Group, please refer to the paper: *Introduction to the ISO 9001 Auditing Practices Group*

Feedback from users will be used by the *ISO 9001 Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised.

Comments on the papers or presentations can be sent to the following email address: charles.corrie@bsigroup.com .

The other ISO 9001 Auditing Practices Group papers and presentations may be downloaded from the web sites:

www.iaf.nu
www.iso.org/tc176/ISO9001AuditingPracticesGroup

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